

Appl. No. to be determined
Communication dated December 30, 2003
Preliminary Amendment and Request to Provoke Interference
Attorney Docket No.: 2183-4041.3US

REMARKS

Applicants present the following remarks pursuant to 37 C.F.R. § 1.607 and herein request that an interference be declared between the above-referenced application and U.S. Patent 6,500,662, issued December 31, 2002, to Calvert *et al.*

Claims 1 through 20 are to be canceled without prejudice or disclaimer. Any fee required but not submitted with this communication may be charged to deposit account no. 20-1469.

The present application is a continuation-in-part of co-pending application U.S. Serial No. 09/874,626, filed June 5, 2001, which is a continuation of Application Serial No. 09/297,535 filed October 12, 1999, now U.S. Patent 6,268,199, which was the National Stage of International Application No. PCT/NL97/00593 filed October 29, 1997, which claims the benefit of EP 96203024.3, filed October 30, 1996.

37 C.F.R. § 1.607:

Pursuant to Rule 607(a)(1), applicants identify U.S. Patent 6,500,662, issued December 31, 2002, to Calvert *et al.* (the '662 Patent) and submit claims for the same, or substantially the same, subject matter, within one year of the issuance of '662 patent in compliance with 35 U.S.C. § 135.

Proposed Count:

Pursuant to Rule 607(a)(2), the applicants propose the language of claim 21 of the instant application to be the count. 37 C.F.R. § 1.607(a)(2). The proposed count reads as follows:

An isolated nucleic acid comprising a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence is SEQ ID NO:24 or a sequence that hybridizes to the complement of SEQ ID NO:24 under conditions comprising hybridization to filter-bound DNA in 0.5 M NaHPO₄, 7% SDS, 1 mM EDTA at 65 °C, and washing in 0.1X SSC/0.1% SDS at 68 °C.

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37 C.F.R. § 1.607(a)(3):

Pursuant to Rule 607(a)(3), applicants identify claims 1 through 6 of U.S. Patent 6,500,662 to Calvert *et al.* as corresponding to the proposed count.

37 C.F.R. § 1.607(a)(4):

Pursuant to Rule 607(a)(4), applicants identify claims 21 through 26 of the instant application as corresponding to the proposed count. These claims read substantially as follows:

21. An isolated nucleic acid comprising a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence is SEQ ID NO:24 or a sequence that hybridizes to the complement of SEQ ID NO:24 under conditions comprising hybridization to filter-bound DNA in 0.5 M NaHPO₄, 7% SDS, 1 mM EDTA at 65 °C, and washing in 0.1X SSC/0.1% SDS at 68 °C.

22. A transfected host cell comprising a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence is SEQ ID NO:24 or a sequence that hybridizes to the complement of SEQ ID NO:24 under conditions comprising hybridization to filter-bound DNA in 0.5 M NaHPO₄, 7% SDS, 1 mM EDTA at 65 °C., and washing in 0.1X SSC/0.1% SDS at 68 °C, which transfected host cell is capable of expressing the encoded North American PRRS virus.

23. An isolated nucleic acid comprising a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence is SEQ ID NO: 24.

24. An isolated nucleic acid in the form of a plasmid, wherein said isolated nucleic acid comprises a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence is SEQ ID NO: 24.

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25. An isolated infectious RNA molecule encoded by an isolated nucleic acid comprising SEQ ID NO: 24, which infectious RNA molecule encodes a North American PRRS virus.

26. A recombinant North American PRRS virus encoded by an isolated nucleic acid comprising a DNA sequence encoding an infectious RNA molecule encoding a North American PRRS virus, wherein said DNA sequence is SEQ ID NO: 24.

Applicants submit that the terminology “nucleic acid” as used in the proposed count and applicants’ claims are the same or substantially the same as “polynucleotide molecule” (as used in claims of the ‘662 Patent). The remainder of the claims are substantially duplicates of the claims in the ‘662 Patent.

In addition, the infectious clone disclosed in the parent application and the present application would presumably hybridize to the complement of SEQ ID NO:1 under the “highly stringent conditions” identified in claims 1 and 2 of the ‘662 Patent.

37 C.F.R. § 1.607(a)(5):

Pursuant to Rule 607(a)(5), applicants point out the following portions of the present application, which provide support for the presented claims.

Basis for applicants’ claim 21 is found throughout the application. Specific basis for the claimed “DNA sequence” can be found in original claim 8 of the parent application, which depended indirectly from claims 5 and 1. Basis for the “encoding a North American PRRS virus” language of claim 21, is provided, for example, at paragraph [0008] of the present application, which describes that the “immunological characterization and nucleotide sequencing of EP and US (or “North American”) strains of PRRSV has identified minor antigenic differences within strains of PRRSV located in the structural viral proteins (Nelson et al., 1993;

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Wensvoort et al., 1992; Murtaugh et al., 1995).” Further basis is provided by the list of PRRSV “or ATCC VR 2332, 2385, VR 2386, VR 2429, and VR 2402”) which describe various U.S. strains of PRRSV. Basis for "wherein said DNA sequence is SEQ ID NO:24 or a sequence that hybridizes to the complement of SEQ ID NO:24 under highly stringent condition" (emphasis added) can be found, for example, at paragraph [0008] of the application, which describes "nucleotide sequencing of EP and US (or “North American”) strains of PRRSV" and paragraph [0003], which describes the "extremely varied and powerful molecular biology techniques aimed at modifying nucleic acids at the DNA level ... [making] it possible to analyze and modify genomes at the molecular level." Basis for SEQ ID NO:24 and the hybridization and washing conditions can be found, for example, at paragraphs [0030] to [0032], which recites SEQ ID NO:24 and the claimed hybridization and wash conditions. In addition, support can be found, for example, at paragraphs [0033 to 0037], which describe the isolation of the 3' and 5' termini, using PCR, which is dependent on hybridization conditions, and sequencing nucleic acids, which is dependent on denaturation and hybridization conditions, all of which are well known in the art.¹

Basis for applicants’ claim 22 is found throughout the application. Specific basis for the claimed “DNA sequence,” hybridization conditions and wash conditions can be found in the application as described for claim 21. Basis for "A transfected host cell" can be found, for example, at paragraphs [0004], [0029] and [0056], which describe host cells and transfection.

Basis for applicants’ claims 23 through 26 can be found, for example, at paragraphs [0030] to [0032], which describe recombinant and isolated PRRSV nucleic acids (for example, SEQ ID NO:24), as well as plasmids.

¹ Hybridization techniques are extremely well known in the art. For example, Ed Southern first developed the blotting and hybridization technique in 1975 (Southern, E.M. (1975) Detection of specific sequences among DNA fragments separated by gel electrophoresis. *J. Mol. Biol.* 98:503-517). In addition, see pages 382 to 389 of Maniatis *et al.* (1982) *Molecular Cloning: A Laboratory Manual* (Cold Spring Harbor Laboratory), which describes a formula for determining the appropriate hybridization and wash conditions.

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37 C.F.R. § 1.607(a)(6):

Pursuant to Rule 607(a)(6) and 35 U.S.C. § 135(b)(1) the applicants have included claims 1 through 6 in the instant application within one year of the issue date (December 31, 2002) of U.S. Patent 6,500,662 B1 to Calvert *et al.*

Applicants note that the application eventually leading up to U.S. Patent 6,500,662 was apparently not earlier published. Therefore, 35 U.S.C. § 135(b)(2) should be inapplicable to the claims of the instant application, which is governed by 35 U.S.C. § 135(b)(1). As noted previously, the claims of the instant application are being filed within one year of the date on which the '662 patent was granted.

37 C.F.R. § 1.607(b):

Applicants note that pursuant to Rule 607(b), examination of the instant application is to “be conducted with special dispatch”.

37 C.F.R. § 1.607(c):

Pursuant to Rule 607(c), applicants submit that claims 1 through 6 of the '662 Patent substantially correspond to claims 21 through 26 of the instant application.

37 C.F.R. § 1.608:

Applicants' US effective filing date, October 29, 1997 (PCT International Application PCT/NL97/00593 (Publication WO 98/18933)) predates by more than one year the December 22, 1998 filing date of U.S.S.N. 60/113,345, the earliest claimed priority date of U.S. Patent 6,500,662 B1 to Calvert *et al.* Accordingly, should an interference be declared, applicants are entitled to judgment relative to Calvert *et al.* and the showing of Rule 608 should be inapplicable to the instant matter.

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Conclusion

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the number given below.

Respectfully submitted,



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